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02-0125 (US02)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Stanley W. Olsen, Jr., et al.** **Serial No.: 10/786,251** **Filed:** February 24, 2004 **For:** RETROGRADE PLUNGER DELIVERY SYSTEM	**Group Art Unit:** 3733 **Confirmation No.:** 2722 **Examiner:** Cumberledge, Jerry L.

AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action, mailed June 27, 2008, please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 8 of this paper.

CERTIFICATE OF TRANSMITTAL

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450 on the date shown below via the USPTO EFS-Web filing system.

	Jocelyn L. Lee Name of Person Mailing Paper
/August 18, 2008/ Date of Deposit	/Jocelyn L. Lee/ Signature of Person Mailing Paper

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the Application.

LISTING OF CLAIMS:

1-47. Canceled.

48. (Currently amended) A method for delivering implant material into body tissue using a cannula and plunger assembly, the cannula comprising a cannula body having a first longitudinal opening and a second transverse opening proximal to the first longitudinal opening, the plunger slidably disposed within a lumen of the cannula body and having an attached pliable sealing member disposed at a distal end, the pliable sealing member having, in an uncompressed state, a diameter that is larger than the diameter of the lumen of the cannula body, the method comprising:

inserting the cannula body into targeted body tissue;

perfusing implant material out of the first longitudinal opening into the tissue while the pliable sealing member is in a first position relative to the cannula body and distal to the first longitudinal opening and distal with respect to the cannula body;

moving the pliable sealing member from the first position to a second position relative to the cannula body, the second position being located within the cannula body and proximal with respect to the first longitudinal opening and distal with respect to the second transverse opening; and

perfusing implant material out of the second transverse opening into the tissue while

the pliable sealing member is in the second position, wherein implant material is substantially prevented from exiting the cannula body via the first longitudinal opening.

49. (Previously presented) The method of claim 50, wherein separating the distal portion from the proximal portion of the cannula comprises severing the distal portion from the proximal portion via a notch disposed in the cannula body.

50. (Previously presented) The method of claim 48, further comprising separating a distal portion from a proximal portion of the cannula body after the implant material is perfused out of the respective first longitudinal and second transverse openings.

51. (Previously presented) The method of claim 48, wherein the implant material is longitudinally perfused out of the cannula body through the first longitudinal opening, and transversely perfused out of the cannula body through the second transverse opening.

52. (Previously presented) The method of claim 48, wherein the cannula body further comprises a third transverse opening proximal to the second transverse opening, the method further comprising:

moving the pliable sealing member from the second position to a third position relative to the cannula body, the third position being located within the cannula body and proximal with respect to the second transverse opening and distal with respect to the third transverse opening; and

perfusing implant material out of the third transverse opening into the tissue while the pliable sealing member is in the third position.

53. (Previously presented) The method of claim 48, wherein the implant material is bone cement.

54. (Previously presented) The method of claim 48, wherein the tissue is bone tissue.

55. (Previously presented) The method of claim 54, wherein the bone tissue is a vertebral body.

56. (Currently Amended) A method for delivering implant material into body tissue using a cannula, the cannula comprising a cannula body having a proximal end, a distal end, and a lumen extending there between and terminating at longitudinal opening at the distal end, ~~and~~ the cannula body further comprising one or more transverse openings, a plunger slidably disposed within the lumen and comprising an attached pliable sealing member having a diameter, in an uncompressed state, that is larger than the diameter of the lumen, the method comprising:

inserting the cannula body into body tissue, the cannula body including a plurality of notches disposed in the wall of the cannula body;

advancing the plunger within the lumen so as to place the pliable sealing member distally with respect to the longitudinal opening;

perfusing the implant material out of the ~~one or more openings~~ longitudinal opening into the tissue; and

retracting the plunger within the lumen so as to place the pliable sealing member proximally with respect to the longitudinal opening;

perfusing the implant material out of the one or more transverse openings into the tissue; and

separating the proximal end from the distal end of the cannula body at one of the plurality of notches.

57. (Previously presented) The method of claim 56, wherein the implant material is bone cement.

58. (Previously presented) The method of claim 56, wherein the tissue is bone tissue.

59. (Previously presented) The method of claim 58, wherein the bone tissue is a vertebral body.

60. (Currently Amended) The method of claim 56, wherein the one or more openings comprises a plurality of openings axially spaced from each other along the cannula body ~~the method further comprising perfusing the implant material out of the plurality of openings into the tissue~~.

61-63. (Canceled)

64. (Previously presented) The method of claim 56, further comprising implanting the distal end of the cannula body within the tissue.

65. (Previously presented) The method of claim 56, wherein the distal end of the cannula body is composed of a biocompatible material

66. (Currently amended) A method for delivering implant material into body tissue using a cannula and plunger assembly, the cannula comprising a cannula body having a distal end opening and a wall opening proximal to the distal end opening, the plunger slidably disposed within a lumen of the cannula body and having an attached pliable sealing member, wherein, in an uncompressed state, the pliable sealing member has a diameter that is larger than the diameter of the lumen of the cannula body, the method comprising:

inserting the cannula body into targeted body tissue;

perfusing implant material out of the distal end opening into the tissue while the pliable sealing member is in a first position relative to the cannula body and distal to the distal end opening;

moving the pliable sealing member from the first position to a second position relative to the cannula body located within the cannula body lumen between the distal end opening and the wall opening; and

perfusing implant material out of the wall opening into the tissue while the pliable

sealing member is in the second position, wherein implant material is substantially prevented from passing the pliable sealing member and exiting the cannula body via the distal end opening.

67. (Previously presented) The method of claim 66, further comprising separating a distal portion from a proximal portion of the cannula body after the implant material is perfused out of the respective distal end and wall openings, the separation effectuated by unscrewing the distal portion from the proximal portion via a threaded junction disposed on the cannula body.

68. (Previously presented) The method of claim 66, further comprising separating a distal portion from a proximal portion of the cannula body at a connective sleeve interposed between the distal portion and the proximal portion, the separation effectuated by applying an external removal force to a connective sleeve.

REMARKS

Claims 48-60 and 64-68 are pending in the Application. Claims 48, 56, 60, and 66 have been amended. Initially, Applicants' gratefully acknowledge that claims 48-55 and 66-68 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. § 112, second paragraph. In this regard, Applicants' have corrected these issues in independent claims 48 and 66.

Independent claim 56 has been amended to include similar claimed aspects found in allowable claims 48 and 66. In particular, claim 56 has been amended to even more particularly recite the claimed feature of the cannula body having a lumen therein that terminates in a longitudinal opening at the distal end. Further, the cannula body comprises one or more transverse openings. A plunger is slidably disposed within the lumen and has an attached pliable sealing member having a diameter, in an uncompressed state, that is larger than the diameter of the lumen. Further, claim 56 has been amended to include the aspect of advancing the plunger within the lumen so as to place the pliable sealing member distally with respect to the longitudinal opening. With the pliable sealing member in this position, implant material is perfused out the longitudinal opening. According to amended claim 56, the plunger is retracted within the lumen so as to place the pliable sealing member proximally with respect to the longitudinal opening. Implant material can then be perfused out of the one or more transverse openings into the tissue. Finally, the proximal end is separated from the distal end of the cannula body at one of the plurality of notches.

In light of the amendments made to independent claim 56, dependent claim 60 has been amended.

§ 112, Second Paragraph Rejections

Claims 48-55 and 66-68 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office Action points out that in both claims 48 and 66 the word "of" appears to have been mistakenly omitted between the word "diameter" and "the." Applicants have corrected this clerical error by amending claims 48 and 66 to include "of" after "diameter." Claims 48 and 66 were also rejected because, according to the Office Action, there is insufficient antecedent basis for "the lumen of the cannula body" recited in this aspect of the claims. Applicants note, however, that prior to the recitation of "the lumen of the cannula body" both claims 48 and 66 recite "a lumen of the cannula body." Because of this, the claimed aspect of "the lumen of the cannula body" refers to the previously introduced lumen of the cannula body found in line 4 of claim 48 and line 4 of claim 66.

Applicants submit that the claims are now in full compliance with § 112, second paragraph.

§ 102(e) & 103(a) Rejections

Claims 56-58, 60, 64, and 65 are rejected under 35 U.S.C. § 102(e) as being anticipated by Margulies et al. Claim 59 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Margulies et al. in view of Reiley et al. In response to this rejection, as stated above, independent claim 56 has been amended to include similar claimed aspects found in (allowable) claims 48 and 66. These claimed aspects are neither disclosed nor suggested by Margulies et al. or Reiley et al.

In particular, claim 56 has been amended to recite the aspect of the longitudinal opening located at a distal end of the cannula body in addition to one or more transverse openings located in the cannula body. Claim 56 now includes the feature of plunger slidably disposed within the lumen and comprising an attached pliable sealing member having a diameter, in an uncompressed state, that is larger than the diameter of the lumen of the cannula body. When the plunger is advanced within the lumen so as to place the pliable sealing member distally with respect to the longitudinal opening, implant material can be perfused out the longitudinal opening into the tissue. The plunger can then be retracted within the lumen so as to place the pliable sealing member proximally with respect to the longitudinal opening whereby implant material can be perfused out the one or more transverse openings into the tissue. The proximal end of the cannula body may be separated from the distal end of the cannula body at one of a plurality of notches located in the cannula body. These features are neither disclosed nor suggested in the Margulies et al. and Reiley et al. prior art references.

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The amendments and remarks presented herein are believed to fully address the outstanding issues set forth in the Office Action and place the claims in condition for

allowance. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (949) 724-1849 (x. 104).

Respectfully submitted,

VISTA IP LAW GROUP LLP

Dated: /August 18, 2008/

By: /Michael S. Davidson/
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